

**REMARKS**

This is a full and timely response to the Office Action mailed July 6, 2005.

By this Amendment, claim 4 has been amended to incorporate the limitations of claims 5 and 6. Further, claims 8-10 have been amended to address the rejection under 35 U.S.C. §112, second paragraph, and to put the claims in better form under U.S. practice. Also, in view of the amendment to claim 4, claims 5 and 6 have been canceled without prejudice or disclaimer to their underlying subject matter. Lastly, claims 1-3, 11 and 15 have been amended in preparation for rejoinder under U.S. practice. Support for the claim amendments can be found variously throughout the specification and the original claims. Thus, claims 1-4 and 7-15 are pending in this application, with claims 1-3 and 11-15 being withdrawn.

In view of these amendments, Applicant believes that the pending claims are in condition for allowance. Reexamination and reconsideration in light of the above amendments and the following remarks is respectfully requested.

**Rejections under 35 U.S.C. §112**

Claim 10 is rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicant respectfully traverses this rejection.

The Examiner expressed concerns in the Action that the “*monoclonal antibody mA116 is required to practice the claimed invention*” and thus, “[A]s a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public”. The Examiner believes that the monoclonal antibody mA116 recited in claim 10 does not appear to be readily available material based on the teachings of the specification and the knowledge in the art.

To address the Examiner’s concerns in this regard, Applicant has provided examples of mA116 scFv Ab and their respective Deposit Accession Numbers. Applicant has also provided a Deposit Declaration as per the Examiner’s request.

Applicant notes that the insertion of the examples of mA116 scFv Ab into the specification does not constitute new matter since the disclosure of such antibodies are found in the reference, Alvi AZ, Hu WG, Fulton RE, Nagata LP, Coles JE, and Long MC: *Functional enhancement of a partially active single chain variable fragment antibody to Venezuelan equine encephalitis virus* Viral Immunology 2003; 16:213-222 (see page 2, lines 15-17, of the

specification), which has been specifically incorporated by reference (see page 18, lines 1 and 2, of the specification).

Applicant also notes that claim 10 now incorporates the limitations of non-rejected claims 5 and 6 in view of the amendments to claim 4.

Thus, withdrawal of this rejection is respectfully requested.

Claims 5 and 7-9 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant respectfully traverses this rejection.

However, in the interest of expediting the allowance of the present application, Applicant has changed the rejected phraseology in claim 5 (now in amended claim 4) from “*an*” to “*the*”, and deleted the term “high” from claims 8 and 9.

Thus, withdrawal of this rejection is respectfully requested.

#### **Rejection under 35 U.S.C. §102**

Claims 4, 7 and 9 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Aubrey et al. (Biol. Chem. 2001, 382:1621-1628). This rejection has been rendered moot by the incorporation of non-rejected claims 5 and 6 into claim 4.

As the Examiner has recognized, the fusion protein of the present invention is entirely different than that of Aubrey et al. First, the fusion protein of the present invention is at least 7 amino acids larger than that of Aubrey et al. Aubrey’s fusion protein consists of scFv + spacer (10 amino acids) + SBP (10 amino acids), while Hu’s fusion protein consists of scFv + 2 spacers (10 amino acids) + SBP (11 amino acids) + 6 His region (6 amino acids). Secondly, the scFv components of Aubrey et al. are obviously different than the scFv components of the present invention since they are reactive to entirely different antigens. Lastly, the amino acid sequences of the protein of Aubrey et al. are completely different than that of the present invention, such as, for example, the former sequence being SAWRHPQFGG, and the latter being PCHPQFPRCYA.

Thus, for these reasons, withdrawal of this rejection is respectfully requested.

**Rejection under 35 U.S.C. §103**

Claims 4 and 7-10 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Alvi et al. (Hybridoma and Hybridomics, 2002, 21(3):169-178) in view of Keefe et al. (Protein Expression and Purification, 2001, 23:440-446) and Aubrey et al. This rejection has also been rendered moot by the incorporation of non-rejected claims 5 and 6 into claim 4.

As the Examiner has recognized, the fusion protein of the present invention is different than that of Alvi et al. Alvi et al teaches an anti-VEE scFv, designated as A116, which was generated from hybridoma cell line 1A4A1. This scFv (A116) was shown to be minimally reactive with target VEE antigen (see page 178, first column, of Alvi et al.). In contrast, the scFv of the fusion protein of the present invention possesses an enhanced reactivity to VEE. The present inventors have engineered a scFv having a difference amino acid sequence than the scFv of Alvi et al. to achieve such an enhanced VEE reactivity.

Thus, withdrawal of this rejection is respectfully requested.

**Request for Rejoinder**

Applicant also hereby formally requests rejoinder of method claims 1-3 and 11-15 under *In re Ochiai* upon the allowance of the elected product claims. Applicant has amended non-elected claims 1 and 11 to depend on claim 4 to thereby include all the limitations of the allowable product claims in accordance with §821.04 of the MPEP. Applicant notes that claims 1-3, 11 and 15 have also been amended to put the claims in better form under U.S. practice.

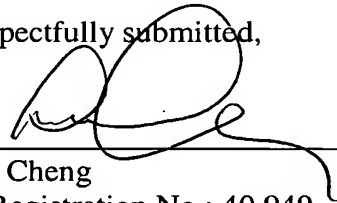
### CONCLUSION

This is in full and timely response to the Notice of Non-Compliance dated December 23, 2005, for which a one-month time period for response was allotted. The present Revised Amendment responds to the Notice of Non-Compliance by providing a complete listing of all of the claims as to comply with the requirements of 37 C.F.R. § 1.121(c). Withdrawal of the finding of non-compliance and entry of the present Amendment is therefore courteously solicited.

All of the claims now pending in the present application are believed to be clearly patentable over the outstanding rejection. Accordingly, favorable reconsideration of the claims in light of the above remarks is courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the below-listed number.

Dated: January 23, 2006

Respectfully submitted,



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